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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,296	05/24/2005	Andreja Vukmirovic	BPPG-32982A/LEK	9213
7590 02/03/2010				
Mark S. Graham, Esq. LUEDEKA, NEELY & GRAHAM, P.C. P.O. Box 1871 Knoxville, TN 37901				
EXAMINER				
HOLLOMAN, NANETTE				
ART UNIT		PAPER NUMBER		
1612				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,296

Applicant(s)

VUKMIROVIC ET AL.

Examiner

NANNETTE HOLLOMAN

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed on December 22, 2009. Applicants' arguments, filed December 22, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 102

Claims 1-13 were rejected under 35 U.S.C. 102(b) as being anticipated by Woog et al. (US Patent No. 4,992,419). This rejection is maintained.

Applicant's Arguments

Applicant argues the transition phrase "consisting essentially of" is adequately elucidated in the instant specification, having been explained as excluding additional EPO stabilizers other than polyvinylpyrrolidone (PVP), and, optionally a poloxamer. Applicant further argues example 5 of Woog et al., which does not list urea, is obviously an error. Applicant's arguments have been fully considered but they are not persuasive.

Examiner's Response

As previously asserted, the term "consisting essentially" is inadequately described by the instant specification, since it fails to contemplate the exclusion of any particular ingredients as implied therein; nor does it provide any criteria for determining if a given ingredient "materially affects the basic or novel characteristics of the invention. Applicant points to the specification at page 5, last paragraph that,

In the pharmaceutical composition of the present invention, besides the pH buffering system and optionally besides an isotonifying agent and/or further pharmaceutically acceptable excipients PVP alone may be used as the effective EPO stabilizer and no further stabilizers are necessary for stabilizing EPO. PVP can therefore replace the combinations of different stabilizers which are known to be used to maintain the EPO stability in pharmaceutical compositions of EPO described in the prior art

would teach that PVP as the primary, and in many cases the only, EPO stabilizer needed in the claimed composition. However, Applicant has failed to show that the introduction of additional components or stabilizers would materially change the characteristics of Applicant's invention. Furthermore, as previously asserted, at page 4, lines 10-25 of the instant specification, Applicant discloses a preferred embodiment of a composition "comprising", which is open language, components a.-c. and optionally d. and e. Furthermore, "consisting essentially of" is being interpreted to mean "comprising", and the addition of urea is still encompassed by the instant claims. In regard to Applicant's assertion that Woog's example 5 is obviously an error, a patent is considered to be valid and therefore EXAMPLE 5 would appear to not contain urea as a stabilizer. Therefore, Woog et al. encompass the limitation of the instant claims.

Claim Rejections - 35 USC § 103

Claims 19-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Woog et al. (US Patent No. 4,992,419) as applied to claims 1-13 above, and further in view of Cymbalista (US Patent No. 4,647,454). This rejection is maintained.

Applicant's Arguments

Applicant argues Woog does not teach PVP and a poloxamer as the sole or even the essential stabilizer for EPO and Cymbalista does not cure the deficiencies of Woog. Applicant argues claims 19 and 20 exclude the use of EPO stabilizers other than PVP and poloxamer teaches a composition in which urea is the principal stabilizer for EPO. Applicant further argues Cymbalista uses PVP to stabilize interferon β , not EPO and one of ordinary skill would recognize that a stabilizer which is effective for one protein may be inappropriate for stabilizing a different protein. Applicant's arguments have been fully considered but they are not persuasive.

Examiner's Response

In regard to Woog et al., see Examiner's Response supra. Furthermore, as disclosed in the Office Action filed October 17, 2008, Woog et al. discloses a composition comprising EPO, PVP (KOLLIDON 12 PF) and buffers in TABLE 1, formulation s1 and b, therefore encompassing the claimed limitations. As previously asserted, the use of "consists" in the body of the claims does not limit the open-ended "comprises" language in the claim. In regard to Cymbalista, as previously asserted,

Cymbalista was used to disclose that PVP has been shown to be a highly effective stabilizer of proteins (column 3, line 67 and Tables 1-6).

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. MPEP 2144.07. Therefore, it would have been obvious to have used PVP as the sole stabilizer of Woog et al. motivated by the desire to use a material known for its stabilizing properties.

In addition, in KSR v. Teleflex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, "obviousness to try" such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to achieve long-term EPO stabilization. Accordingly, it would have been obvious to have tried the stabilizer PVP in the formulation of Woog et al. motivated by the desire to achieve maximum stability as disclosed by Cymbalista.

Claims 1-15 and 19-21 are pending.

Claims 1-13, 19 and 20 are rejected.

Claims 14, 15 and 21 are withdrawn.

No claims allowed.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **NANNETTE HOLLOMAN** whose telephone number is (571) 270-5231. The examiner can normally be reached on Mon-Fri 800am-500pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612